K012571

NOV 0 7 2001

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

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Date Prepared: August 7, 2001

Trade Name: Reprocessed Harmonic Scalpels

Classification Name: Electrosurgical cutting and coagulation device and Accessories

Classification Number: 21 CFR 878.4400

Product Code: LFL

Predicate Device(s): The reprocessed harmonic scalpel is substantially equivalent to the Harmonic Scalpel Hs2 Blade (K941897), manufactured by Ethicon (formerly Ultracision); Reusable Laparosonic Blade System (K930352), manufactured by Ethicon (formerly Ultracision); and the counterpart devices from the original manufacturer.

Device Description: Harmonic scalpels are part of an ultrasonic system and are intended to be used in soft tissue surgery for simultaneous cutting and hemostasis. The system consists of a generator/foot switch, handle, connecting hose, and a scalpel blade. Only the handle and scalpel blade are reprocessed. The generator/foot switch and hose components of the device are not included as part of this submission.

Harmonic scalpels can be manufactured using aluminum with a nickel chrome alloy edge or a titanium alloy (with or without a coating.) These scalpels are available in a variety of lengths, outer circumferences, angles, and sharpness.

Intended Use:

The reprocessed harmonic scalpels are intended for use in soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or a substitute for electrosurgery, lasers, and steel scalpels in abdominal, pediatric, gynecological and other endoscopic procedures.

Functional and Safety Testing:

Representative samples of reprocessed harmonic scalpels underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products reprocessed.

Conclusion:

The reprocessed harmonic scalpel is substantially equivalent to Harmonic Scalpel Hs2 Blade (K941897), manufactured by Ethicon (formerly Ultracision); Reusable Laparosonic Blade System (K930352), manufactured by Ethicon (formerly Ultracision); and the counterpart devices from the original manufacturer. This conclusion is based upon the devices' similarities in functional design, materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

Mr. Patrick Fleischhacker
Vice President Regulatory and Quality Control
SterilMed, Inc.
11400 73rd Avenue, North
Minneapolis, Minnesota 55369

Re: K012571
Trade Name: Reprocessed Harmonic Scalpels
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: LFL
Dated: August 7, 2001
Received: August 9, 2001

Dear Mr. Fleischhacker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker MP

Celia M. Witten, Ph.D., M.D.
for Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Page

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Device Name: Reprocessed Harmonic Scalpels

Indications for Use:

The reprocessed harmonic scalpels are intended for use in soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or a substitute for electrosurgery, lasers, and steel scalpels in abdominal, pediatric, gynecological and other endoscopic procedures.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walker

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012571